

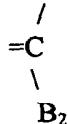
**Listing of Claims:**

1. (Currently Amended) A method of reducing the risk eliminating the onset of Type 1 diabetes in a predisposed human patient by up to 90 percent, comprising the steps of:  
~~identifying a human patient predisposed to Type 1 diabetes patient, wherein Type 1 diabetes is detectable in a patient with autoantibodies to  $\beta$  cell antigens; and~~  
orally administering to the patient an effective amount of a  $1\alpha$ -hydroxy vitamin D compound such that the risk of onset of Type 1 diabetes or Type 1 diabetes symptoms is reduced eliminated.
2. (Original) The method of claim 1 wherein the compound is selected from the group consisting of  $1\alpha,25$ -dihydroxyvitamin D<sub>3</sub> ( $1,25$ -(OH)<sub>2</sub>D<sub>3</sub>),  $19$ -nor- $1,25$ -dihydroxyvitamin D<sub>2</sub> ( $19$ -nor- $1,25$ -(OH)<sub>2</sub>D<sub>3</sub>),  $24$ -homo- $22$ -dehydro- $22E$ - $1\alpha,25$ -dihydroxyvitamin D<sub>3</sub> ( $24$ -homo- $22$ -dehydro- $22E$ - $1,25$ -(OH)<sub>2</sub>D<sub>3</sub>),  $1,25$ -dihydroxy- $24(E)$ -dehydro- $24$ -homo-vitamin D<sub>3</sub> ( $1,25$ -(OH)<sub>2</sub>- $24$ -homo D<sub>3</sub>),  $19$ -nor- $1,25$ -dihydroxy- $21$ -epi-vitamin D<sub>3</sub> ( $19$ -nor- $1,25$ -(OH)<sub>2</sub>- $21$ -epi-D<sub>3</sub>),  $1\alpha$  hydroxy vitamin D<sub>3</sub> or  $1\alpha$  hydroxy vitamin D<sub>2</sub>.
3. (Previously Amended) The method of claim 1 wherein the vitamin D compound is selected from the group consisting of vitamin D compounds with the following formula:

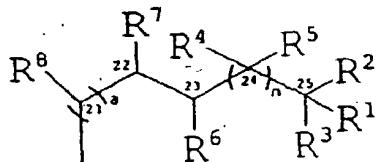
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wherein X<sup>1</sup> and X<sup>2</sup> are each selected from the group consisting of hydrogen and acyl; wherein Y<sup>1</sup> and Y<sup>2</sup> are each selected from the group consisting of H, 0-aryl, 0-alkyl, aryl, and alkyl of 1-4 carbons, taken together to form an alkene having the

structure of B<sub>1</sub>



where B<sub>1</sub> and B<sub>2</sub> are selected from the group consisting of H, alkyl of 1-4 carbons and aryl, and can have a  $\beta$  or  $\alpha$  configuration; Z<sup>1</sup>=Z<sup>2</sup>=H or Z<sup>1</sup> and Z<sup>2</sup> together are =CH<sub>2</sub>; and wherein R is an alkyl, hydroxyalkyl or fluoroalkyl group, or R represents the following side chain:



wherein (a) may have an S or R configuration, R<sup>1</sup> represents hydrogen, hydroxy or O-acyl, R<sup>2</sup> and R<sup>3</sup> are each selected from the group consisting of alkyl, hydroxyalkyl and fluoralkyl, or, when taken together represent the group-(CH<sub>2</sub>)<sub>m</sub>-wherein m is an integer having a value of from 2 to 5, R<sup>4</sup> is selected from the group consisting of hydrogen, hydroxy, fluorine, O-acyl, alkyl, hydroxyalkyl and fluoralkyl, wherein if R<sup>5</sup> is hydroxyl or fluoro, R<sup>4</sup> must be hydrogen or alkyl, R<sup>5</sup> is selected from the group consisting of hydrogen, hydroxy, fluorine, alkyl, hydroxyalkyl and fluoroalkyl, or R<sup>4</sup> and R<sup>5</sup> taken together represent double-bonded oxygen, R<sup>6</sup> and R<sup>7</sup> taken together form a carbon-carbon double bond, R<sup>8</sup> may be H or CH<sub>3</sub>, and

wherein n is an integer having a value of from 1 to 5, and wherein the carbon at any one of positions 20, 22, or 23 in the side chain may be replaced by an O, S, or N atom.

4. (Original) The method of claim 1 wherein the oral administration is via diet.

5. (Original) The method of claim 1 wherein the oral administration is at the concentration of between 0.005  $\mu$ g to 0.2  $\mu$ g per kilogram of patient weight per day.

Claims 6 – 10 (Cancelled)

11. (New) A method of reducing the risk of Type 1 diabetes in a predisposed human patient by up to 90 percent, comprising the steps of:

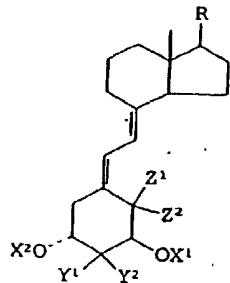
identifying a human patient predisposed to Type 1 diabetes, wherein Type 1 diabetes is detectable in a patient with autoantibodies to glutamic acid decarboxylase; and

orally administering to the patient an effective amount of a  $1\alpha$ -hydroxy vitamin D compound such that the risk of onset of Type 1 diabetes or diabetes symptoms is reduced.

12. (New) The method of claim 11 wherein the compound is selected from the group consisting of  $1\alpha,25$ -dihydroxyvitamin D<sub>3</sub> ( $1,25$ -(OH)<sub>2</sub>D<sub>3</sub>), 19-nor- $1,25$ -dihydroxyvitamin D<sub>2</sub> (19-nor- $1,25$ -(OH)<sub>2</sub>D<sub>3</sub>), 24-homo-22-dehydro-22E- $1\alpha,25$ -dihydroxyvitamin D<sub>3</sub> (24-homo-22-dehydro-22E- $1,25$ -(OH)<sub>2</sub>D<sub>3</sub>), 1,25-dihydroxy-24(E)-dehydro-24-homo-vitamin D<sub>3</sub> (1,25-(OH)<sub>2</sub>-24-homo D<sub>3</sub>), 19-nor- $1,25$ -dihydroxy-21-epi-vitamin D<sub>3</sub> (19-nor- $1,25$ -(OH)<sub>2</sub>-21-epi-D<sub>3</sub>),  $1\alpha$  hydroxy vitamin D<sub>3</sub> or  $1\alpha$  hydroxy vitamin D<sub>2</sub>.

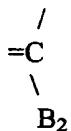
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13. (New) The method of claim 11 wherein the vitamin D compound is selected from the group consisting of vitamin D compounds with the following formula:

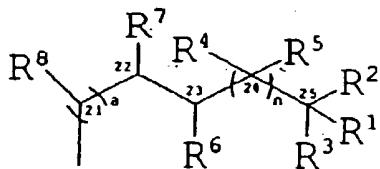


wherein  $X^1$  and  $X^2$  are each selected from the group consisting of hydrogen and acyl; wherein  $Y^1$  and  $Y^2$  are each selected from the group consisting of H, 0-aryl, 0-alkyl, aryl, and alkyl of 1-4 carbons, taken together to form an alkene having the

structure of  $B_1$



where  $B_1$  and  $B_2$  are selected from the group consisting of H, alkyl of 1-4 carbons and aryl, and can have a  $\beta$  or  $\alpha$  configuration;  $Z^1=Z^2=H$  or  $Z^1$  and  $Z^2$  together are  $=CH_2$ ; and wherein R is an alkyl, hydroxyalkyl or fluoroalkyl group, or R represents the following side chain:



wherein (a) may have an S or R configuration,  $R^1$  represents hydrogen, hydroxy or O-acyl,  $R^2$  and  $R^3$  are each selected from the group consisting of alkyl, hydroxyalkyl and fluoralkyl, or, when taken together represent the group- $(CH_2)_m$ -wherein m is an integer having a value of

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from 2 to 5, R<sup>4</sup> is selected from the group consisting of hydrogen, hydroxy, fluorine, O-acyl, alkyl, hydroxyalkyl and fluoralkyl, wherein if R<sup>5</sup> is hydroxyl or fluoro, R<sup>4</sup> must be hydrogen or alkyl, R<sup>5</sup> is selected from the group consisting of hydrogen, hydroxy, fluorine, alkyl, hydroxyalkyl and fluoroalkyl, or R<sup>4</sup> and R<sup>5</sup> taken together represent double-bonded oxygen, R<sup>6</sup> and R<sup>7</sup> taken together form a carbon-carbon double bond, R<sup>8</sup> may be H or CH<sub>3</sub>, and wherein n is an integer having a value of from 1 to 5, and wherein the carbon at any one of positions 20, 22, or 23 in the side chain may be replaced by an O, S, or N atom.

14. (New) The method of claim 11 wherein the oral administration is via diet.

15. (New) The method of claim 11 wherein the oral administration is at the concentration of between 0.005 μg to 0.2 μg per kilogram of patient weight per day.